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SUMMARY OF SAFETY AND EFFECTIVENESS

Date: April 22, 1996


Company: Physiometrix, Inc.
Five Billerica Park
101 Billerica Avenue
N. Billerica, MA 01862

Contact: Dawn E. Frazer
Director, Regulatory Affairs & Quality Assurance
(508) 670-2422
(800) 474-9746

Subject Device: Model 1220 , OR e-Net (54 - 62 cm)

Predicate Device: K930080, HydroDot NeuroMonitoring System

Classification: Class II, CFR 21 Part 882.1320, Cutaneous Electrodes

Description:  The OR e-Net is designed to fit patients with a head size in the range of 54 - 62 cm in circumference. It is constructed using the same materials and manufacturing processes as the predicate device, Large e-Net which is described in K930080.

Intended Use: The e-Net serves two functions as a part of the Hydro Dot NeuroMonitoring System. First, it locates the EEG electrodes according the 10-20 International System. Secondly, it conducts the electrical signal sensed by the electrodes from the skin to the EEG equipment.

Indication for Use: EEG recording in OR environment.

Design/Materials: The OR e-Net is fabricated from the same materials as the larger version. Two changes were made to make the product more suitable for the OR environment. First, the material located below the ear was removed and secondly, theinion tab was extended to allow it be secured to the neck.